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INFO RUEAUSA/DEPT OF HHS WASHINGTON DC
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RHHMUNA/HQ USPACOM HONOLULU HI
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RUEHBK/AMEMBASSY BANGKOK 8079
RUEHBY/AMEMBASSY CANBERRA 1008
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USAID FOR ANE/CLEMENTS AND GH/CARROLL
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SUBJECT: AMBASSADOR DISCUSSES SAMPLE SHARING AND VACCINE WITH BAXTER
VACCINES PRESIDENT

¶1. (SBU) Summary. The President of Baxter Bioscience's Vaccine Business, Kim Bush, told the Ambassador on August 14 that he believes the Indonesians would welcome a solution to the AI virus sample sharing impasse. Negotiations among a smaller group of key stakeholders could best resolve the issue. He identified possible steps including use of existing domestic industry-government agreements that would provide a reasonable royalty arrangement, such as the 0.5 percent royalty paid to sample suppliers in certain protocols. Bush also described the status of Baxter's human AI vaccine and current negotiations with the Government of Indonesia (GOI), including their possible involvement in clinical trials and the development of a downstream "fill and finish" vaccine production partnership. Baxter requested that the Embassy urge key WHO officials to visit commercial laboratories, such as Baxter's U.S. facilities, to witness cell culture vaccine-based technology for possible application in developing countries. End Summary.

Sample Sharing Impasse

¶2. (SBU) Based on numerous Baxter-GOI meetings, Bush offered insights into the GOI perspective on sample sharing. In his opinion, multilateral discussions have stalled and negotiating positions are widening rather than narrowing. Bush urged that the USG consider quiet, focused discussions involving key Indonesian officials and fewer international players. Solving a complex problem on the public stage is not conducive to a quick resolution to the impasse, since the media are following the issues closely. Bush noted that fewer people away from the public eye would allow for calmer fact-based negotiations and would more likely result in real progress.

¶3. (SBU) In addition to GOI concerns about access to a pandemic vaccine for its population and a share of commercial rewards or success, Bush emphasized the importance of respect. He felt that a Washington-initiated invitation to key GOI figures would go a long way in building up better relations for a faster and more productive resolution to the impasse.

¶4. (SBU) Bush also noted that the GOI appears naive in its understanding of the commercial vaccine business. Bush explained

that Dr. Triono Soendoro, Director of the GOI National Institute of Health Research and Development and other key MOH figures have never had the experience of working out material transfer agreements (MTAs) with industry. They don't have a sense of realistic royalty sharing, nor an appropriate model text. Although GOI officials have ideas of what they want to see in a final agreement, they don't know how to reasonably get there. Bush recommended that negotiators find a commercial precedent that works and adapt it in Indonesia. For example, he noted that domestic U.S. pharmaceutical producers pay a 0.5 percent royalty to sample suppliers in certain protocols. Baxter has previously worked arrangements with the U.S. NIH and the U.S. Centers for Disease Control (CDC). Bush felt that if negotiators provided the GOI with fact-based information on how business works and how governments can license technology, sample sharing negotiations could move forward faster. However, Bush did not offer ideas of how this could be worked within the context of WHO influenza surveillance network.

Baxter-MOH Negotiations

15. (SBU) Bush clarified the terms of the Baxter-GOI MOU. Despite press articles to the contrary, Bush noted that Baxter has never received virus samples directly from MOH, nor is the company seeking virus samples in the future. Baxter is committed to working exclusively through the WHO collaborating centers to acquire virus strains. Bush explained that Baxter developed the AI vaccine from the Indonesian strain that used CDC-released samples from 2005, not later samples. Baxter has completed initial testing in Europe, with Phase II clinical trials in Hong Kong and Singapore to be completed by the end of the month. Baxter intends to conduct a pediatrics trial and a Phase III trial prior to releasing the vaccine. Baxter

JAKARTA 00002230 002 OF 002

has offered Indonesia a chance to participate in the Phase III trial but contrary to MOH press statements, has not yet reached any agreement.

16. (SBU) Bush clarified that the Baxter-MOH MOU signed in February is simply a framework agreement that will incorporate future agreements addressing specific issues such as technology transfer for downstream production of vaccine. Bush noted that the Baxter MOU only references bulk vaccine transfer for a "fill and finish" production partnership. The GOI recognizes its own limitations for vaccine development and is not seeking anything beyond a bottling role in vaccine production.

17. (SBU) Bush also asked the Embassy's help in urging WHO to do field site visits to better understand cell-culture based vaccine technology. Bush noted that WHO remains dubious about the application of cell-culture vaccine technology for application in developing countries but that this technology was of critical importance to meeting global demand in the event of a pandemic. Bush reported that Baxter had invited WHO officials to tour Baxter laboratories to better understand the merits of this new technology.

18. (SBU) Bush summarized that Baxter does not want to find itself in the crossfire between Indonesian and WHO negotiations but would be willing to play a constructive role, as appropriate. Baxter wants quick resolution of the sample sharing impasse in order to be able to obtain current samples from WHO collaborating centers. Bush pledged to continue to communicate with the Embassy in order to help all parties understand the industry position.

19. (SBU) Comment: Embassy believes Baxter officials are operating in good faith with their recommendations. Embassy concurs that getting key policymakers to meet away from the public eye may be more effective in hammering out resolution to the myriad of sample sharing issues. Embassy also believes that if one of the Indonesian key issues (for example, a royalty sharing arrangement along the lines of those already in use with other sample suppliers) could be separated out from the others for priority discussion and perhaps resolution, the MOH may be persuaded to resume sample sharing while remaining issues are still under discussion.

